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EDITORIAL

How can we Introduce New Technology Safely and Effectively?

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Introduction

The article on the U.K. Registry for the Endovascular Treatment of Aneurysms (RETA) in this month's edition of the Journal[1] raises questions about the value of such registries. The wider issues concerning the evaluation of new technology also require discussion.

Throughout Europe, regulations exist to prevent the use of new drugs until their safety and effectiveness have been proved. However, until recently there were no regulations regarding the introduction of new interventional procedures and the technology associated with them. The uncontrolled introduction of new technology without proper evaluation has caused serious problems. The complications associated with the hasty adoption of laparoscopic cholecystectomy led to much adverse publicity.[2] Unfortunately, vascular surgeons and radiologists do not appear to have learned from the mistakes made by their general surgical colleagues. Endovascular aortic aneurysm repair (EVAR) holds great promise for clinicians and patients alike. However, the desire for publicity and financial reward has led to its uncritical adoption by many centres.[3] The disintegration of some first-generation aortic stent grafts has recently caused great concern.[4]

On 1st January, 1995 a new European directive covering implantable medical devices became effective. This required all medical devices to bear a CE mark from 14th June, 1998. The CE mark indicates that the device meets the essential safety requirements. Many countries in the European Union have reorganised their ministries of health to implement these directives. In the U.K. the responsible "competent authority" is the Medical Devices Agency, which delegates operational responsibilities to independent organisations (notified bodies) such as The British Standards Institute.[5]

The European directive covers only safety, not efficacy, and concern remains about the uniformity of safety standards imposed by individual countries.[6] In the U.K. the Government's Advisory Committee on Science and Technology recommended the establishment of "a committee on safety and efficacy of procedures to review and register novel surgical procedures" with statutory powers similar to the Committee for Safety of Medicines.[7] The Department of Health rejected this proposal in favour of a voluntary system of registration, established under the auspices of the Medical Royal Colleges.[8] The Safety and Efficacy Register of New Interventional Procedures (SERNIP) classifies new procedures as follows:

(a) Safety and efficacy established; procedure may be used.
(b) Sufficiently close to an established procedure to give no reasonable grounds for questioning safety and efficacy, procedure may be used.
(c) Safety and efficacy not yet established: procedure requires a fully controlled evaluation and may be used only as part of systematic research comprising either an observational study (ci) or a randomised controlled trial (cii).
(d) Safety and/or efficacy shown to be unsatisfactory: procedures should not be used.

SERNIP liaises with the Standing Group on Health Technology Assessment (HTA) regarding funding of research for unproven procedures. SERNIP has classified endovascular AAA repair as cii and the HTA has now funded a multicentre, randomised trial of

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EVAR vs. conventional AAA repair in the U.K. Other countries including France and Netherlands have similar organisations and may fund similar trials.[9] Although SERNIP is voluntary, many health authorities in the U.K. will not fund procedures in Category (d), and only those in Category (c) if part of a study or trial. The newly created National Institute for Clinical Excellence does have the power to veto the use of new drugs or technology on a cost-effectiveness basis. This has raised accusations of rationing on cost grounds alone.[10]

The Joint Working Party of the Vascular Surgical Society of Great Britain and Ireland and the British Society of Interventional Radiologists agreed principles regarding the introduction of EVAR in 1996.[11] These principles stated that EVAR should be assessed initially in centres that satisfied certain criteria including:

- Clear evidence of association between Vascular Surgeons and Vascular Radiologists.
- Specific training in EVAR before embarking upon independent practice.
- Adequate workload in terms of conventional repair and acceptable mortality.
- A detailed audit of results and submission of data to a central registry (RETA).

The purpose of the Registry was to facilitate efficient, timely analysis of outcomes and thereby permit early, wider dissemination of EVAR, subject to the results from the pilot centres being satisfactory. The voluntary nature of the registry raises questions about the completeness and accuracy of the returned data.[12] However, checks with commercial companies suggest a data return rate of about 90% of the devices implanted in the U.K. Conformity with the Registry was further improved by the decision of the EVAR Trial Management Committee to use RETA as the "front door" to entry into the randomised trial and data from the Registry contributed to the successful funding of the EVAR Trial. Therefore, the Registry appears to have fulfilled its original aims and we must now wait for the results of randomised trials before further expansion of EVAR is permitted. The Eurostar Registry has also provided valuable information about stent-graft disintegration and endoleaks.[13]

The HTA recently addressed the issue of when and how to assess fast-changing technologies.[14] They recommended early assessment and emphasised the importance of addressing any financial implications from the outset. The "gold standard" for the assessment of any new intervention remains the randomised controlled trial (RCT). However, the conventional RCT seems very inflexible.[15] Randomising a new technology against conventional treatment may jeopardise the results if carried out too early but delaying the start of randomisation may risk loss of clinical equipoise, i.e. the surgeon and/or patient will no longer accept the conventional treatment. Russell and others have argued for more pragmatic trials.[16] The tracker trial design advocated by Lilford *et al.*[17] incorporates some degree of flexibility that adapts the trial protocol to changes in new technology whilst retaining the advantages of a RCT. Tracker trials possess the following features:

- Early randomisation of new treatments by all centres performing them.
- A flexible protocol without a prefixed sample size or trial duration.
- Monitoring of treatments and centres to provide an early warning system.

The U.K. EVAR Trial incorporates some elements of tracker trial design. The Trial Management Committee will evaluate new devices and centres for inclusion into the trial and the Trial Monitoring Committee will monitor devices and centres for adverse events.

With the advent of tracker trial and other pragmatic designs there seems little excuse for surgeons or commercial companies to avoid early formal assessment of new technology and interventions. However, such assessment will usually require a large multicentre trial and funding at a national or European level may take years to obtain. The proposal that commercial companies should contribute financially to such trials seems controversial and beyond the scope of this article. In the meantime, registries such as RETA will continue to have a place as a means of gathering early data, free of individual or commercial bias. National Vascular Societies and the European Vascular Society should promote and support such registries, which can facilitate the funding of subsequent randomised trials.

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